



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

NOV 4 2004

1461 06 07-8 2344

Frederick S. Mayer, R.Ph., M.P.H.
Pharmacists Planning Service, Inc.
101 Lucas Valley Road
Suite 210
San Rafael, CA 94903

Docket Number: 2001P-0075/CP2

Dear Mr. Mayer,

This letter responds to your citizen petition dated May 12, 2004, requesting that the Food and Drug Administration (FDA or the Agency) switch the emergency contraceptive drug Plan B (levonorgestrel, 0.75 mg) to over-the-counter (OTC) status.

I am writing to inform you that we have not yet resolved the issues raised in your petition because it identifies significant matters requiring extensive review and analysis by Agency officials. This interim response is provided in accordance with FDA regulations on citizen petitions (21 CFR 10.30(e)(2)). We will respond to your petition as soon as we have reached a decision on your request.

Sincerely,

Jane A. Axelrad
Associate Director for Policy
Center for Drug Evaluation and Research

2001P-0075

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